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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,607	12/12/2001	Darcy Wayne Greep	14458.41	7181

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EXAMINER	
ROANE, AARON F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 09/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/021,607	GREEP ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-10,12-20,22-24,26-29,33-38,40,41 and 43-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-10,12-20,22-24,26-29,33-38,40,41 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-5, 7, 14, 15, 17-20, 22, 23, 40, 41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (USPN 6,132,427) in view of Okajima (USPN 5,554,139).

Regarding claims 1, 2, 14, 17, 22, 40, 41 and 43, Jones et al. discloses an electrosurgical tip having a multi-layer conductive coating and disclose the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-31. Jones et al. fail to explicitly disclose a hand piece configured to receive RF energy. However, the absence of an explicit recitation of a hand piece is due to the inherency of the hand piece. Additionally Jones et al. fails to disclose a multi character coated electrode tip and explicitly recite that the multicharacter material is a block copolymer of a hydrophobic monomer or polymer and a hydrophilic monomer or polymer. Okajima discloses a medical instrument (catheter) and teaches that the instrument is coated with "a block-

copolymer formed by a hydrophilic compound block and a hydrophobic compound block" in order to serve as a lubrication layer, see col. 9, line 66 through col. 10, line 7. The fact that Okajima discloses a coating having hydrophilic material that can be interpreted at attracting water and Applicant's assertion on page 9, ¶ 030, lines 4-8, that a multicharacter material that attracts water to the surface and lubricates the surface creates a low shear, sacrificial layer. The recitation of lubricious nature of the polymer coating meets the claimed limitation. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Jones et al., as taught by Okajima, to coat the instrument with "a block-copolymer formed by a hydrophilic compound block and a hydrophobic compound block" in order to serve as a lubrication layer.

Regarding claim 3, Jones et al. discloses the claimed invention, see col. 4, lines 18-23.

Regarding claim 4, Jones et al. disclose the claimed invention.

Regarding claims 5, 15, 18 and 19, Jones et al. teaches the inclusion of a conductive tip comprising a porous metal of roughened stainless steel, see col. 7, lines 22-26, col. 5, lines 1-7 and figures 5 and 6, element 130 and claim 25.

Regarding claims 7 and 23, Jones et al. disclose the claimed invention, see col. 3.

Regarding claim 20, Joes et al. disclose the claimed invention, see col. 3, lines 16-24.

Claims 29, 34, 35, 44, 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (USPN 6,132,427) in view of Okajima (USPN 5,554,139) in further view of Layrolle et al. (USPN 6,207,218 B1).

Regarding claims 29, 35, 44 and 47, Jones et al. discloses an electrosurgical tip having a multi-layer conductive coating and disclose the method, step or use of a device including a multi-layered coated tip electrode with a base coating (16) of ceramic in order to provide a wear resistant cover, see col. 3, lines 4-31. Jones et al. fails to disclose a multi character coated electrode tip and explicitly recite that the multicharacter material is a block copolymer of a hydrophobic monomer or polymer and a hydrophilic monomer or polymer and that the multi-character coating is done by the process of electrophoresis that draws the multi-character material into at least a portion of the pores. Okajima discloses a medical instrument (catheter) and teaches that the instrument is coated with "a block-copolymer formed by a hydrophilic compound block and a hydrophobic compound block" in order to serve as a lubrication layer, see col. 9, line 66 through col. 10, line 7. Finally, Layrolle et al. disclose a method of coating medical devices and discloses that it is well known in the art that coating maybe accomplished through "plasma and flame spraying, electrophoresis, dip coating and magnetron sputtering," see col. 2, lines 27-32. Layrolle et al. simply illustrate the alternative coating methods. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the

invention of Jones et al., as taught by Okajima, to coat the instrument with "a block-copolymer formed by a hydrophilic compound block and a hydrophobic compound block" in order to serve as a lubrication layer, and as further taught by Layrolle et al., to use the electrophoresis coating process in as one possible coating method.

Regarding claims 34 and 46, Jones et al. disclose the claimed invention, see col. 3.

Claims 8-10, 12, 13, 16, 24 and 26-28, are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (USPN 6,132,427) in view of Okajima (USPN 5,554,139) as applied to claims 1, 2 17 and 22 above, and further in view of Fan et al. (USPN 5,295,978).

Regarding claims 8 and 9, Jones et al. in view of Okajima disclose the claimed invention except for explicitly reciting that the coating further comprises a water-soluble polymer comprising at least one of: polyethylene oxide, polyethylene glycol or a copolymer of ethylene oxide. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method of coating objects (including catheters, see col. 4) with a water-soluble polymer material which "becomes lubricious when exposed to body fluid." Finally Fan et al. teach a method and use of "poly(ethylene oxide)" as the water-soluble polymer (an atom polymer) in order to overcome the shortcomings of earlier coating polymers, see col. 3,

lines 28-43. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Jones et al. in view of Okajima, as taught by Fan et al. to use "poly(ethylene oxide)" as the water-soluble polymer (an atom polymer) in order to overcome the shortcomings of earlier coating polymers.

Regarding claims 10 and 24, Jones et al. in view of Okajima disclose the claimed invention except for the water soluble polymer having "a radical scavenger that reduces damage to the base layer material during a process of gamma sterilization." Fan et al. teach a method and use of providing a large number of coatings and their equivalence, including a polymer coating containing "organic radicals," see col. 5, lines 7-66. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Jones et al., as taught by Fan et al., to alternately use a large number of polymer coatings some including "organic radicals." The examiner interprets radical scavengers, organic radicals and a radical as the same, i.e., a chemical unit that functions as a single unit, is chemically inalterable and has an unpaired electron. Since Fan et al. disclose so many alternative polymer coatings (as does Applicant), the disclosure of Fan et al. actually teaches an equivalence of the variety of polymer coatings. Additionally, the phrase "that reduces damage to the base layer material during a process of gamma sterilization" is intended use, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claims 12, 13, 27 and 28, Jones et al. in view of Okajima and in further view of Fan et al. disclose the claimed invention. Fan et al. teaches the use biocompatible polymeric abrasion resistant surfaces including formulated additives with antimicrobial or other pharmaceutically effective agents" in order to overcome the shortcomings of earlier coatings and provide a more varied method and wider range of coatings and their properties, see col. 2, lines 43-68.

Regarding claims 16 and 26, Jones et al. in view of Okajima and in further view of Fan et al. disclose the claimed invention. Fan et al. teach the method, step or device that includes a metallic or ammonium ion, co. 5, lines 41-68 and col. 6, lines 1-3.

Claims 33, 37, 38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jones et al. (USPN 6,132,427) in view of Okajima (USPN 5,554,139) in further view of Layrolle et al. (USPN 6,207,218 B1) as applied to claims 29 and 44 above, and further in view of Fan et al. (USPN 5,295,978).

Regarding claims 33 and 45, Jones et al. in view of Okajima and in further view of Layrolle et al. disclose the claimed invention except for explicitly reciting that the multi-character material comprises a charged unit. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in

order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method of coating objects (including catheters, see col. 4) with a water-soluble polymer material which "becomes lubricious when exposed to body fluid." Finally Fan et al. teach the method, step or device that includes a metallic or ammonium ion, co. 5, lines 41-68 and col. 6, lines 1-3. Therefore at the time it would have been obvious to one of ordinary skill in the art to modify the invention of Jones.et al. in view of Okajima in further view Layrolle et al., as taught by Fan et al., to add a charged unit to the coating.

Regarding claim 37, Jones et al. in view of Okajima and in further view of Layrolle et al. disclose the claimed invention except for explicitly reciting that the coating further comprises a water-soluble polymer comprising at least one of: polyethylene oxide, polyethylene glycol or a copolymer of ethylene oxide. Fan et al. teach the method, step and use of a device that is coated with a combination of hydrophilic and hydrophobic polymers in order to provide a abrasion resistant coating to overcome the shortcomings of earlier coatings, see, col. 1, lines 7-22, col. 3, lines 31-40 and claims 1 and 5. Additionally, Fan et al. teach the method of coating objects (including catheters, see col. 4) with a water-soluble polymer material which "becomes lubricious when exposed to body fluid."

Regarding claim 38, Jones et al. in view of Okajima and in further view of Layrolle et al. and in still in further view of Fan et al. disclose the claimed invention. See Fan et al. claims 1 and 5.

Response to Amendment

The examiner acknowledges the amendments to the claims and the submission of the terminal disclaimer.

Applicant has noted and remarked about the lack of explicit recitation of "block-copolymer" in the previously made rejection. Therefore, the examiner has provided additional art (Okajima) to explicitly demonstrate that the block copolymerization of hydrophilic and hydrophobic compounds is known in the art. This further combination is further motivated in that both Fan et al. and Okajima both discuss coating catheters.

Additionally, the previously double patenting rejections of claims 29, 33-35, 37, 38 and 44-47 are removed due to the terminal disclaimer. However, upon further review and an updated search, new art has been provided show that the electrophoresis coating method is just one of many coating methods known in the art and it would therefore be obvious to one of ordinary skill in the art to use electrophoresis.

This rejection is non final.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (703) 305-7377. The examiner can normally be reached on 9am - 5pm, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (703) 308-0994. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A.R.
August 31, 2004

MICHAEL PEFFLEY
PRIMARY EXAMINER